

EXHIBIT 211



Operation One Cardinal Health Quality Management Meeting

Opportunity Team Presentations

13 - 14 Jan 2005



Operation One Cardinal Health Audit and Compliance

Team:
Gary Dolch - Corporate
Tony Esposito - Corporate
John Ficalora - PTS: BSLS
Kim Arnold - PTS: Pharm Dev
Paula Espada - PTS: PR Pkg
Jerry Webb - MPS
Bill Murphy - CTS
Pam Altizer - ATK/George Group

Audit and Compliance Team Objectives

Hypothesis –

- Strengthening internal capabilities in Audit, Compliance Analysis and corporate regulatory counsel for medical devices will cost less than using outside consultants and legal counsel and in the long term will provide CAH the internal capability needed for regulatory compliance.

Work Plan -

The team gathered data on the following :

- Current Audit Program (schedule, staffing, Guest Auditor Program)
- Spending to date on Regulatory Consultants used for compliance analysis or to remedy a problem
- Spending to date on outside legal counsel across all segments

The team also examined:

- Capabilities in EH&S and Due Diligence



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Building Audit and Compliance Capability

Benefits:

- **Cost** : Avoidance of \$5.0M and Lost Earnings of \$10M
 - Avoid Lost Earnings: \$10.0 M
 - Avoid Corrective Action Costs: \$1.0M
 - Avoid Legal costs: \$0.5M
 - Avoid Consultant costs: \$3.5 M
- **Quality Impact** – elimination of disruptive regulatory issues, ability to correct problems, achieve baseline EHS capability, understand risks.
- **Service Impact** – eliminate risks to strategic initiatives, aligns acquired operations to standards, enables influencing regulatory policy

Costs: Ongoing costs of \$0.9M (6 FTEs) and one time costs of \$0.2M for audit verifications

Recommendations:

1. Establish medical device regulatory counsel
2. Establish compliance analysis capability
3. Establish EH&S audit and metric capability
4. Add corrective action and facility operations capability



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Audit Program Findings

- Corp – In FY'04, Moorestown Packaging components, Guaynabo PR (Packaging Component and NPS Headquarters in Los Angeles) were not audited due to staffing shortages
- Guest Auditor Program – difficulty in confirming commitment of time from qualified guest auditors many months in advance causes inability to staff audits appropriately.
- Need for 3rd party to validate CAH Audit Program and update documentation. Results can be used with customers to offset need for customer system audits. Estimated one-time cost of \$200K.

	# times an audit or special investigation could have been done to help diagnose a problem	# Times an Internal auditor could have been employed to help develop or supervise or oversee the implementation of corrective action
Corporate	0	Assessment - Humacao Sterile, Woodstock, Limoge
PTS - BSLs	In FY04, sites needed more outside help because of lack of specific expertise. For situations requiring specific expertise the Corporate auditors may not be the right resource. A good estimate is between 5 and 10 situations per year per site where specific outside help could be used.	Site should be staffed to oversee corrective action on their own. However, specific external expertise has been used in Woodstock, Humacao and Raleigh over the last year as the Quality units are being developed. Again, for situations requiring specific expertise the Corporate auditors may not be the right resource.



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The business investment of \$0.9 M per year to strengthen audit and compliance capability will prevent future cost avoidance in consultant spending, legal costs and lost earnings

Consultant Spending –

- Outside costs to help diagnose or fix problems was \$ 1.1M in FY04 and \$ 3.5 M YTD FY05

Segment	FY 04	FY 05	Consultant Spending
PTS	\$1.110K	\$3,487K	Woodstock FY'04 \$652; Air dispersions, Satellite, ASI & PRFC, FY'05 Quality System Re-engineering, \$1083K, other \$500K – Review of validation docs, mgmt of Validation area & QA director
- Woodstock	\$652K	\$1,583K	
- Albuquerque	\$158K	\$ 204K	
- Puerto Rico	\$300K		
- Humacao Site Assessment Plan		\$1,700K	PR: Humacao Site Assessment Plan = \$1.3M for SOP writing, Aseptic process training, project management, airflow studies, management of the micro lab, Preventative maintenance and QA director.
CTS		\$25K C \$35K Other	MHRA: \$15K for testing and consultant fees, \$30K for travel and \$5K for Label changes (WM email)
Total	\$1.110K	\$3,547K	



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In FY'04, expenses of \$0.5 M were spent in legal costs and \$1.5M on corrective action costs

Costs	FY 04	YTD FY 05
Corporate Legal Costs	\$0.5 M	\$276K
Corrective Action Costs	\$1.0 M	
Total	\$1.5 M	\$276K

- In addition, \$10M in earnings was identified from loss sales due to quality issues

Customer(*)	Issue	Impact in lost revenue
Eli Lilly	Gemzar - Powder in a bottle	\$4.5M lost sales; \$27M in bids lost
Watson	Delayed release	\$2M lost business
Merck	Inventory Maintenance	\$7M in new work lost
Wyeth	Loss of sterile business	\$25M / yr lost to competitor



(*) Source - Customer data received from PTS Go-to-Market Team interviews

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Recommendation to strengthen Audit and Compliance capabilities

Recommend following 6 headcount additions:

- 1 FTE – Legal counsel for medical devices
- 2 FTE – Audit Program
- 1 FTE – In-house Compliance analysis
- 2 FTE – EHS

Timing – March '05



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Enterprise Training Initiative Quality/Regulatory *

cGMP and Related Subject Matter

***Hereafter referred to as Project IMPACT**

13 Jan 2005

Mary Foster, Team Lead, PTS
Steve Reardon, PD
Regina Reilly, PTS
Diane Hernon, CTS

Chris Anderson, MPS
Elaine Labach, PTS
Stefano Arena, PTS
Pam Altizer, Consultant

IMPACT Agenda

Overview/Recommendations/Strategic Drivers
Future State & *The Site, The BU & The BSegment*
The Organization/Advisory Groups
Example of the Benefits: MPS/PD
Risk Analysis/Benefits
Closing Comments/Implementation Plan
Appendix



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Overview/Recommendations for One Cardinal Health cGMP & Related Training

Title: IMPACT

Timing: FY '05-Q4

Purpose: To meet regulatory requirements, exceed customer expectations and ensure compliance to internal procedures. Most importantly, if we look at costs, quality and service levels, the goals with IMPACT will be to really hit the quality and service level touch points. IMPACT will provide a network of resources (e.g. experts for writing materials & presentations; curricula development & course materials; methods for effectiveness evaluation) for improved education in more efficient ways (e.g. timing; standards) without infringing on current accountability & ownership structures at the sites/business units (BU)

Benefits: Initially \$985.7K minimally, in current costs from one example [MPS/PD]; improvement in final product quality and regulatory outcomes [soft \$ in cost avoidance]

Costs: \$871K annually (salaries only) + \$300K (start-up cost)

Recommendations: 1) To establish enterprise program for cGMP and related training; 2) Begin with development of a shared MPS/PD web-based training (WBT) curriculum; and, 3) To establish advisory groups to facilitate execution



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IMPACT & Cardinal Health Strategic Drivers

Operational Excellence Implement and sustain a systematic education approach to build process consistency, competitive advantage, move closer to world class performance and regulatory compliance. *[Excel at every capability we offer.]*

Provide global targeted audience with key regulatory tools, knowledge, expectations and skills.

Harmonize best practice for training techniques and programs while promoting collaboration and continuous improvement. *[Think and act as a team.]*

Leadership Development Improve the ability of employees to perform their jobs. This will increase employee motivation and work satisfaction and thereby, improve customer satisfaction. *[Obsess about execution.]*

Produce accountability & connect learning to business bottom-line. A comprehensive education program can provide valuable feedback for performance reviews.

Educate staff at all sites about CardinalHealth. *[Be personally knowledgeable about our entire offering. Know our internal customers better than they know themselves.]*



Enable us to achieve strategic goals/realize critical success factors

IMPACT & Cardinal Health Strategic Drivers

Growth Revenue increased because less OE issues and increased business/decreased business costs.

Customer Focus Reduce regulatory compliance issues, such as regulatory inspection observation letters/commitments, customer complaints, customer audit observations and investigations that negatively impact the business and our ability to maintain customer's trust and loyalty. *[Make it easy for our customers to do business with us.]* Customers have high expectations of our finished good products and our employees; being well trained is essential to do their jobs and meet customer expectations.

Meet or exceed customer expectations to proactively seek solutions for a customer issue rather than have the customer dictate a solution. Have a work force that can work on 'its feet' instead of have customers come in and meet with us all day to tell us how to solve a problem. *[Know our customers better than they know themselves.]*



Enable us to achieve strategic goals/realize critical success factors

Future State: IMPACT

Recommendations: Enterprise program; MPS/PD example; advisory groups

Site Activities

Continue to identify site training needs; continue implementation of training; continue develop training effectiveness abilities

Site's do not lose control of their training activities; but, rather, will co-develop & implement guidelines & core curricula to further develop their programs; be involved in final outcomes

BU/Segment Activities

Continue to coordinate & align training to unit & segment level pm, as well as recommend curricula & course shells to sites for delivery &, in some cases continue to assess delivery methods (VBT vs. ILT)

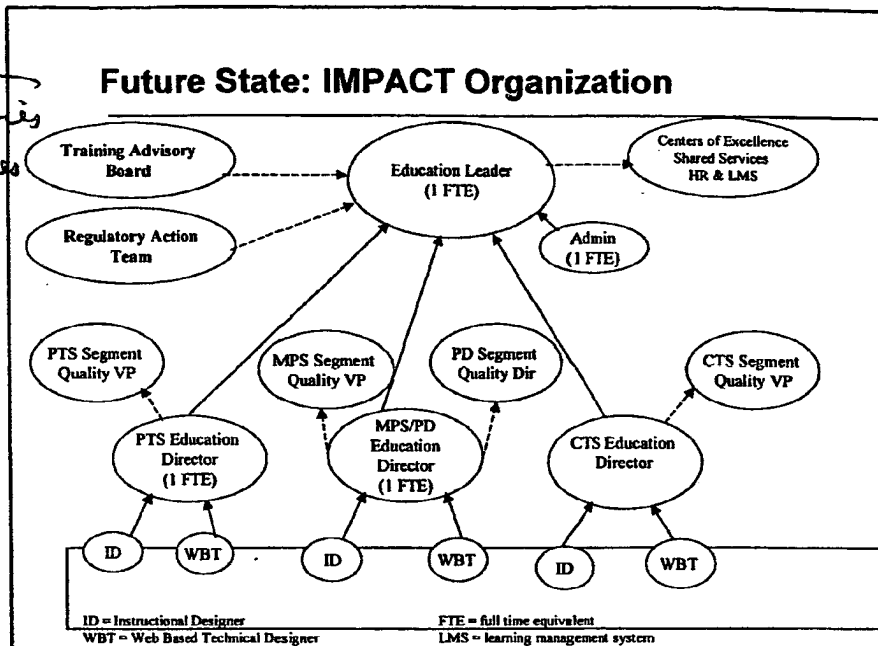
BU's do not lose control but, rather, are expected to continue with their ownership and accountability for educating their employees; IMPACT will guide best practice to improve business outcomes

Enterprise Activities

Establish guidelines for steps in a best practice training process; determine synergies within curricula; develop & evaluate training material/work with sites/units as necessary for pm materials/delivery; maintain Portal for materials & trend metrics

CardinalHealth guides a unified program to improve the business outcomes associated both directly & indirectly with the cGMP education of its employees

Position
Needs
Roles + responsibilities
Core competencies



IMPACT: Advisory Groups

Group	Training Advisory Board (TAB)	Regulatory Action Team (RAT)
Role	Provides support/oversight on IMPACT needs. Develop guidelines & support the adoption of plans at CardinalHealth sites.	To identify and discuss current regulatory action at the federal level that would impact education endeavors throughout the enterprise and establish guidance program to ensure appropriate education is on-going with these issues.
Responsibility	Develop guidelines around various aspects of IMPACT goals including: training effectiveness, trainer qualifications, instructional design, course development, e-learning software and platforms, etc. Provide guidance on core courses, pilot/beta-testing for new concepts & support the portal; review metric trends & help develop actions for improvements.	Review corporate policies as well as BSegment policies to ensure education activities are adequate and make recommendations to improve. Review current regulatory activities across the world and recommend training feedback to ensure compliance is maintained from site to site across all business segments. Act as Expert consultant to the IMPACT leadership in the review of materials and make recommendations for improvements to on-going courses. Also serves as a conduit of information relative to customer concerns such that a problem at one site can be studied and prevented at all other sites.
Group Leader	Education Leader; with each BU providing at least 2 Board members with 1 on for 2 years and 1 on for 1 year to keep a rotation of new and old mixed.	Education Leader; membership TBD

Example of the Benefits: Shared MPS/PD cGMP & Related Training

- **Over 75** QRA and EHS training curriculum topics can be shared between the 84 MPS and PD Distribution Centers.
- **Capital – FY'05:** \$167,000 capital needed for training PC's at all distribution centers, software, and hardware.
- **Incremental Expenses** (contractor, software training, and travel): FY '05: \$30,000 (\$21,500 contractor; \$3500 software training; \$5000 travel).
 - NOTE: MPS Distribution already has budgeted \$30,000 for the CBT project for FY'05. This is a request for an additional \$30,000 from MPS / PD for FY'05
 - FY '06: \$120,000 (\$106,500 contractor; \$3500 software training; \$10,000 travel)
 - FY '07 and beyond: \$60,000 (\$55,000 contractor and \$5000 travel)
- **Project must begin** in February/March with financial investments for savings to be realized in FY'06
- **Need to identify** a shared resource [recommend following program plan – hire Training Director for MPS / PD]



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Benefits of MPS / PD Training Synergy

- **Sharing curriculum** between MPS and PD delivered via CBT / WBT will free supervisor's time to focus on productivity
- CBT / WBT will **improved productivity** through a 49% savings in labor for training by switching from classroom training (\$985,729 per year)
- **50% higher learning retention**
- **Increased consistency** of training delivery; WBTs can replace selected instructor-led classes to achieve learning efficiencies (note: 90% WBT substitution for MPS/PD)
- **Increased efficiency and effectiveness;** WBTs can be developed for selected site course deficiencies to reduce compliance risk
- **Resources freed** from MPS/PD curriculum sharing can be eliminated/redeployed for increased productivity and cost efficiency; positions can be redeployed to satisfy new regulatory training organization needs



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Risk Assessment

Cardinal Health trending:

176 total findings *relative to training* (may be primary or secondary root cause of finding; includes regulatory agencies, internal audits and customer findings from 1/1/02 – 12/7/04)

Jan '01-May '04 FDA analysis of 483s

San Juan district: #1 most common observation 321/614 – failure to follow SOP or to document according to SOP. A core course could be developed to cover this with every employee on a routine basis. The 7th most common 483 was training – cGMP training is inadequate.

Trending data provided to FDA by Turbo

To take quick action relative to next inspection; just so, we need our trends reviewed and acted on...the RAT would provide the insight into our concerns & IMPACT would provide the services necessary to educate staff JIT

Industry Warning Letter excerpts:

1. "There is no documentation that management reviewed the adequacy of the training... or to show that technician was retrained after making multiple errors in QC testing..."
2. "Failure to have in place an adequate organizational structure and sufficient personnel..."
3. "You failed to specify how initial training of new employees would be conducted..."
4. "The training program fails to assure your employees are trained in their specific tasks and in their assigned responsible functions."



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Benefits: IMPACT

Quality & Service Level improvements that will continue to develop as the program delivers (measured & trended; not easily, but will be defined up-front); and, improve costs (again, less easily measured; examples will be repositied but can be exemplified in direct impact by decreased duplication of efforts to develop and in some instances present; web takes place of trainer presenting and indirectly by less OT for re-work)

Improved effectiveness of training through standard program of lesson plans, development of 'core' courses ensuring availability to all, testing & follow-up training prn. Ability to provide a wide range of course materials at a decreased cost based on quantity (on-site, web-casts, awareness of FDA web based training etc.); work with HR and with Cardinal University for synergies [in continuing to develop the right culture and long term improvements]; provide publications for continual feedback & to build or maintain momentum around IMPACT activities; & diversity of courses including customized to business/site needs, CD, videos, web-based employee led; web-based outside contractor led; EduNeering courses

Consider internal transfer of existing employees to build internal capabilities; move their current responsibilities to staff within / reshuffle the deck to best fit



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Closing Comments: IMPACT

- Implementation Plan
- Estimated Costs
- High Level Project Plans



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Closing Comments: IMPACT Implementation Plan to Close The Gap

- Ensure highest level commitment to make IMPACT a reality (a real cultural change from today's model in many sites); determine best method of assurance of success with site/unit/segment leaders such as inclusion in '06 MBO's
- Fill leadership role
- Define thorough project business centric plan which aligns with leadership SAP/goals - 5 objectives discussed:
 - 1) develop educational training standards
 - 2) prioritize educational needs
 - 3) determine global learning objectives
 - 4) identify training resources & methods
 - 5) conduct educational activities
- Form advisory groups (TAB and RAT)



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Closing Comments: IMPACT Costs to Close the Gap



Enterprise Education Organization*:

• Education Leader	\$155,740
• Administrative Asst	\$ 43,680
• Segment Directors (3)	\$402,870
• ID/WBT at business level (4)	<u>\$268,360</u>
Estimated Annual Costs:	\$870,650

MPS/PD Curriculum Alignment:

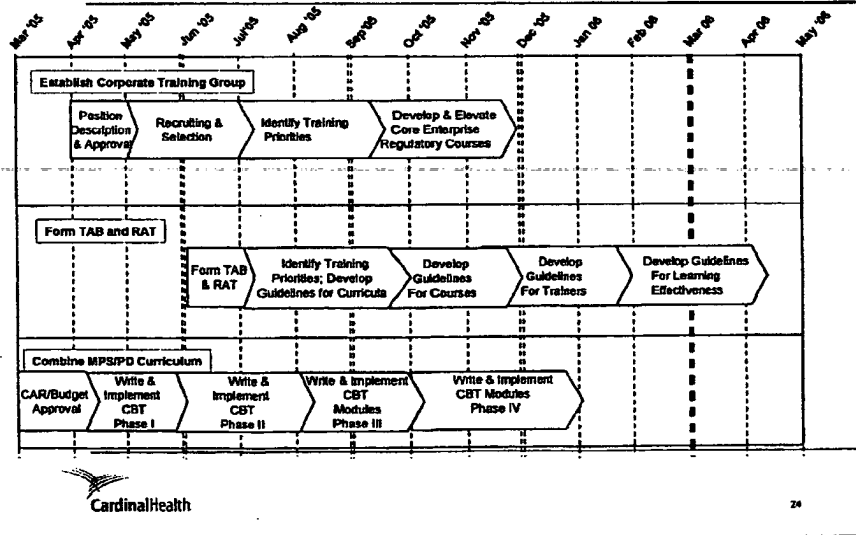
• PCs for Distribution Centers (estimated one-time cost)	\$300,000
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* Salaries represent band midpoints for pay market B and include 30% for benefits.
* Estimated salaries do not include other expenses and travel.

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Closing Comments High Level Project Plans



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Appendix

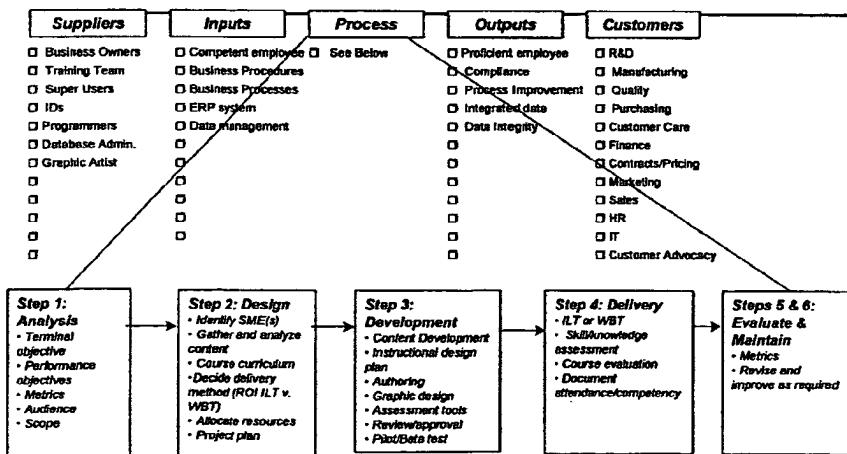
- I. SIPOC/Gaps
- II. RACI
- III. Current state/problems

* Current curriculum summary available upon request



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SIPOC (Suppliers - Inputs - Process - Outputs - Customers)



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Regulatory Training Gaps Based on SIPOC

	Step 1 – Analysis of Training Needs	Step 2 – Design Curriculum	Step 3 – Develop Course Materials	Step 4 – Deliver Training	Step 5 – Evaluate Training	Step 6 – Maintain Materials & Metrics	
Corporate Segment	Guidelines to ID minimum training requirements	Guidelines on trainer qualifications, LMS, and curricula	Guidelines for instructional design plan, course design and training effectiveness	Guidelines for trainer certification and use of WBTs	Guidelines on min. metrics at corp. level and updating course materials	Need portal for storage of courses and other information	Corporate, Segment & Business Level: <i>Large gaps in most steps of training process</i>
Business	ID/prioritize training needs and evaluate effectiveness	Guidelines on recommended curricula	Guidelines on learning assessment; provide course 'shells' to sites	ROI decision on WBT vs. ILT; guidelines on TTT to sites to support course delivery	Guidelines on revision process and min. metrics at business level	Need LMS that tracks training and meets regulatory requirements	Site Level: <i>Gaps from inconsistent course development and delivery</i>
Site	ID site-specific training needs and execute to guidelines	Develop site-specific curricula and execute to guidelines	Review and approve course content and execute guidelines	Certify trainers, materials and execute course evaluation process	Collect and assess training outcomes against goals and baseline	Ensure training materials are current, correct and available	



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RACI for IMPACT

Activities	Training Leader	Advisory Boards	Segment Training Director
Set policies	A-Set /A-Execute	C-Set/C-Execute	R-Set/R-Execute
Establish guidelines	A	R	C
Assess for WBT	R	C	A
Needs Assessment	A-Core Curricula R-Other	C-Core Curricula C-Other	R-Core Curricula A-Other
Design	A-Core Courses C-Other	C-Core Courses C-Other	R-Core Courses A-Other
Development	A-Core Courses C-Other	C-Core Courses C-Other	R-Core Courses A-Other
Delivery	A-Core Courses C-Other	C-Core Courses C-Other	R-Core Courses A-Other
Evaluation	A-Core Courses R-Other	C-Core Courses C-Other	R-Core Courses A-Other



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FY'05 Current State and Estimated Regulatory Training Costs

No standardized training process (e.g. needs evaluation, metrics, training effectiveness, or trainer certification etc.)

PTS – Inconsistent training across sites

MPS / PD – Redundant training across sites; high potential for resource sharing

CTS – Training teams embedded in businesses; solid program in place to date

Segment	Estimated Regulatory Training Costs	Estimated FTE's by Activity ²
CTS	\$ 877,100	61.60
PTS	\$1,624,200 ¹	62.86
MPS	\$1,766,500	100.64
PD	\$ 246,200	20.10
Totals	\$4,514,000	245.20

Footnotes:

1. Training costs exclude salaries. Internal costs consisting of training delivery support (material prep and logistics) and external costs consisting of travel, trainer/enrollment fees and materials (note: costs exclude salaries/labor hours of trainees).
2. FTEs by Activity collected from OCH Quality Shared Services Survey Attachment B and includes quality, administration and operations line and management FTEs, and include edited adjustments.

Current State – Problems/Issues

Lack of corporate sponsorship for training; authority (if there is any real accountability) rests at individual sites in most cases; in most cases no repercussions for problems in training (not showing up; not completing; failing testing)

Training process is **non-existent** in some sites

Numerous 483 references to insufficient training [one of root causes or symptom of causes: Staff not trained; Trainers not qualified; effectiveness was not measured; Training not provided in a timely manner; curriculum not developed or no minimum training requirements]

Redundant training across most segments with little to no resource sharing

Training is **outsourced** or ILT (Instructor Led Training). In many cases WBT would drastically reduce training costs.



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Thanks for Listening

Any questions?

What are your concerns?



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Operational Excellence

Team Members

- Sally Grigoriev – CTS
- Alan Barnebey – CTS
- Greg Baumli – MPS
- Jerry Webb – MPS
- Clive Pepper – PTS
- Bill Bolding – PTS, Packaging Services
- Frank Harmon – PTS, Sterile
- Laura Jones – PTS, Development
- Bill Owad – QRA, team lead
- Pam Altizer – ATK / George Group, support team
- Stratford Sherman - Prescient Leaders LLC, support team



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The Imperative of Operational Excellence

Operational Excellence: The attainment of a competitive advantage that is sustained by delivering exceptional performance that creates superior customer value.

Operational Excellence integrates the three realms of quality



- Customer Satisfaction: Service Excellence has been shown to influence as much of 40% of EBIT for Cardinal Health
- Performance Excellence: There are variable levels of performance that result in missed customer expectations and extra cost
- Compliance: Is a minimum requirement



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Cardinal Health's Program Foundations

- Customer Driven Operational Excellence builds on Cardinal Health's core values of ethics, collaborative values, innovation and partnering
- Establishes a process to identify improvement opportunities that directly support achieving One Cardinal Health strategies
- Serves as a clear bridge between internal work and external customer value
- Improves and optimizes processes to reduce waste, lower overall costs, accelerate process cycle times, minimize variation and improve compliance
- Focuses on key measurements, baselines and desired rates of improvement
- Creates an infrastructure to implement process improvements that are customer driven and enable sustained results to achieve "Double in Four"



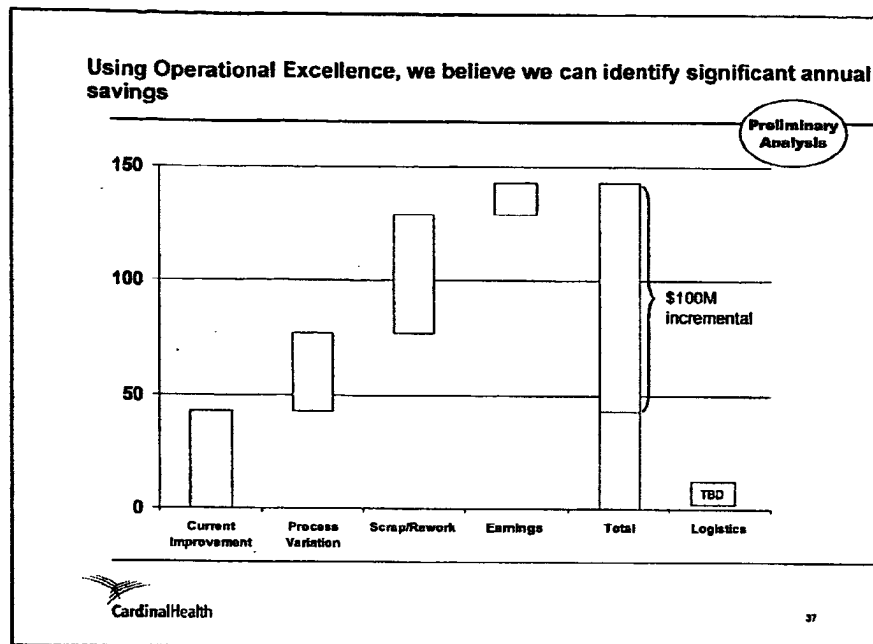
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Our Burning Platform

- Loss of credibility, financial value
- Emphasis on ethics (form vs substance)
- Return to mid teen's earnings in FY'06 and beyond.
- Need to understand quality from customer's perspective
- Inability to achieve unrealized potential
- Limited on growth until organization is integrated internally through cultural development
- Build a new culture of winning
- Re-energize the organization



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Approaching Organizational Engagement

Macro Change (Organization)

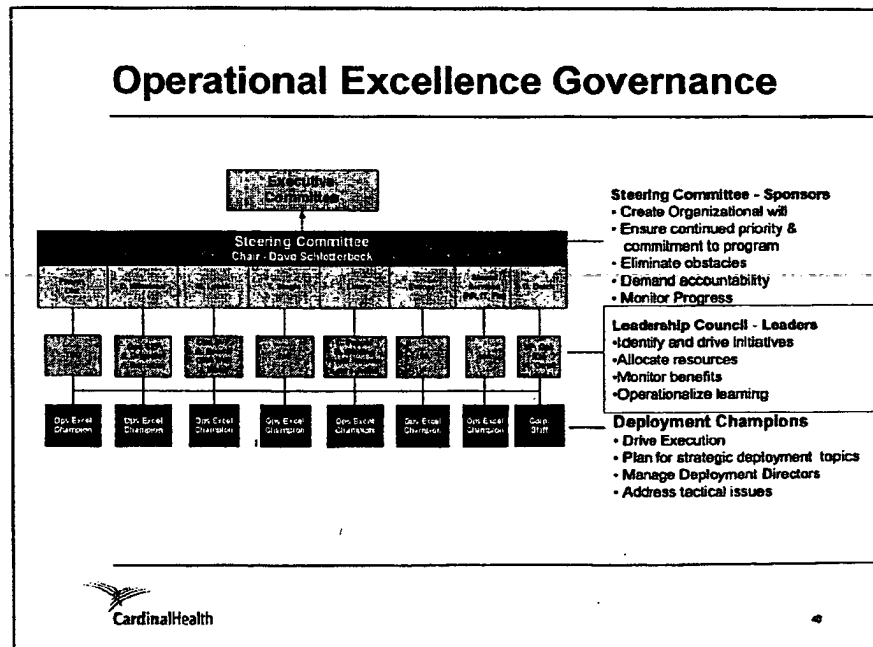
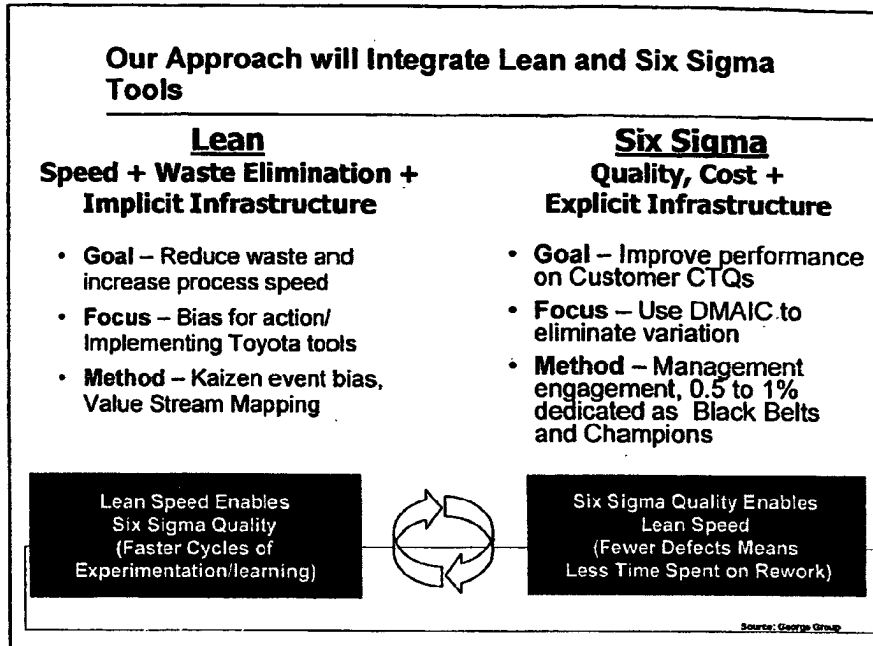
- Assess the cultural and organizational barriers/resistance
- Provide role-specific experiential training to broaden understanding and base of support
- Provide the key influencers (80/20) with coaching / support so they can apply central LSS concepts within their areas
- Key influencers model the desired future state by "walking the talk"
- Convey a consistent message of top-down support for LSS
- **Critical to getting the change started**

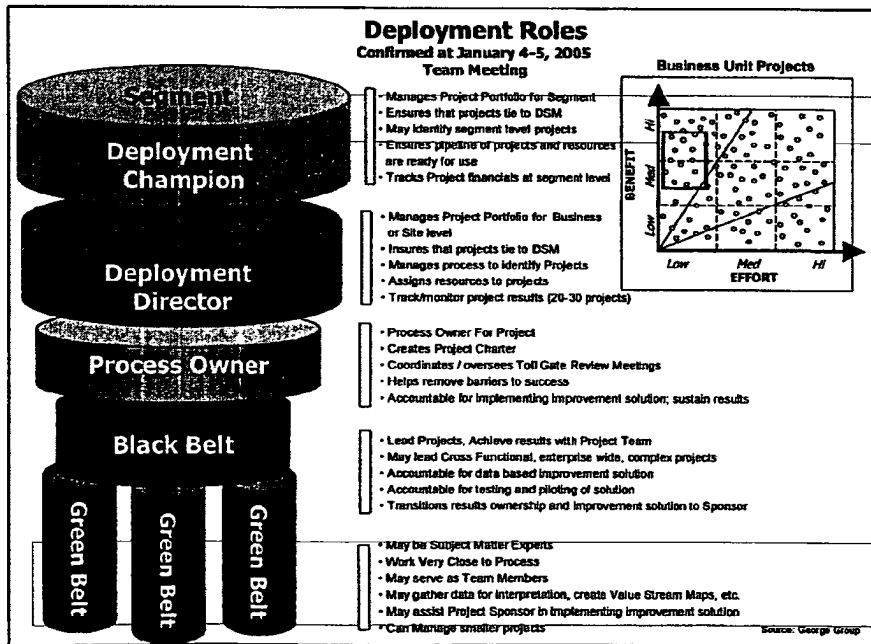
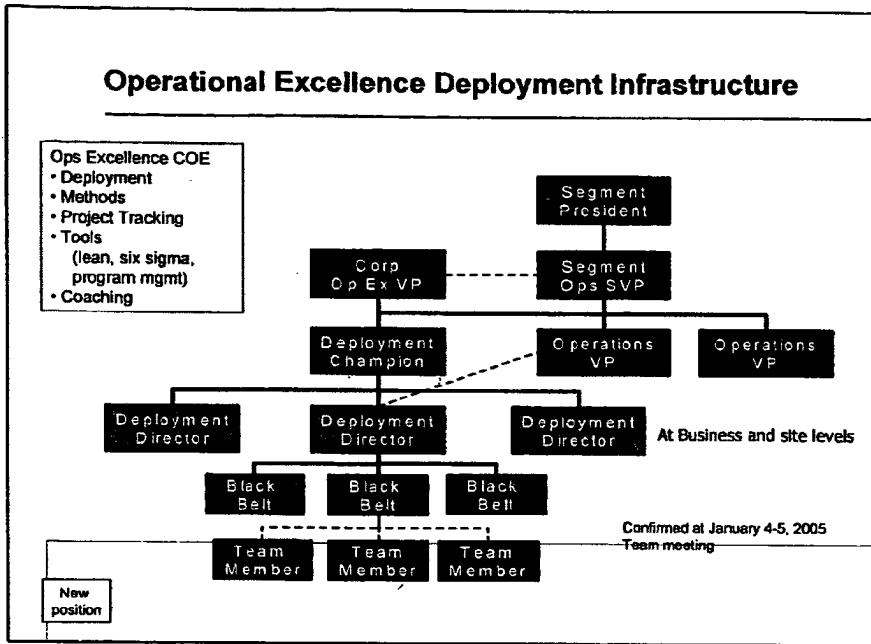
Micro Change (Project Level)

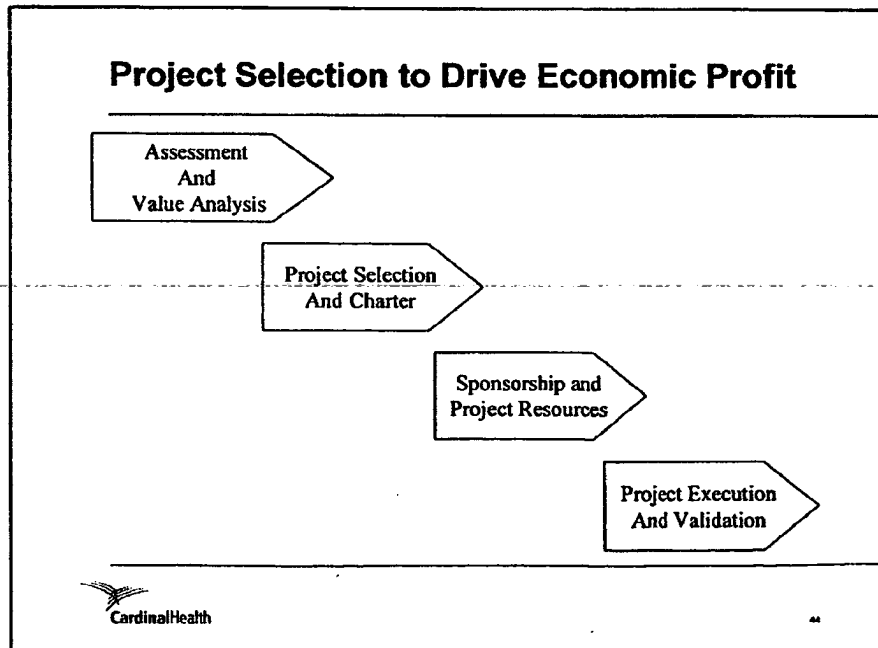
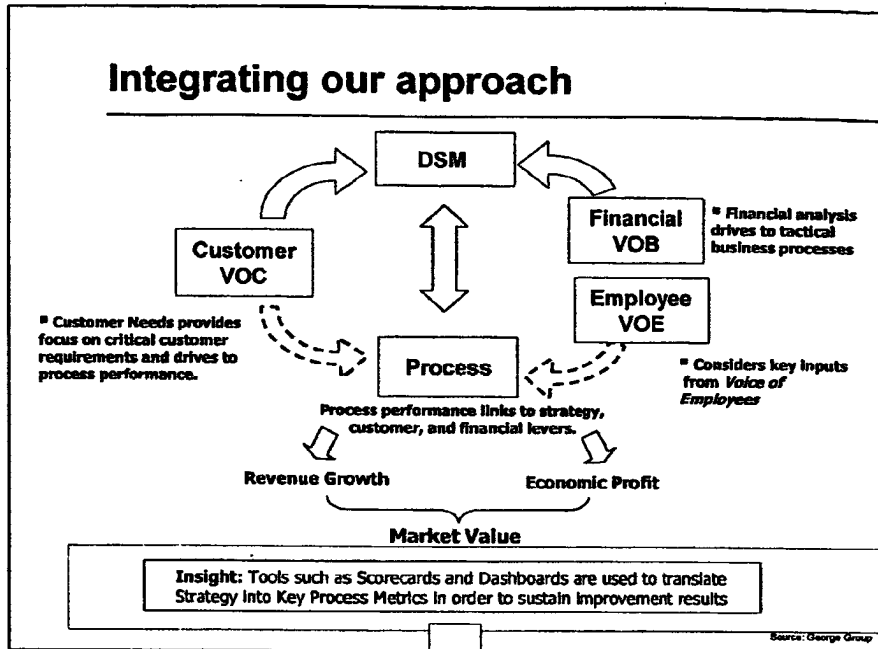
- Classroom training provides Black Belts / Green Belts and Sponsors with the tools to execute the project
- Team members get "on the job" training through the Black Belts (with the support & guidance of a coach)
- Projects are selected which cure "persistent pain" within the business
- Project successes are recognized and disseminated by senior managers
- Committed team members and sponsors form the pool of future Black Belts and Green Belts
- **Critical to building the momentum that will sustain the change**

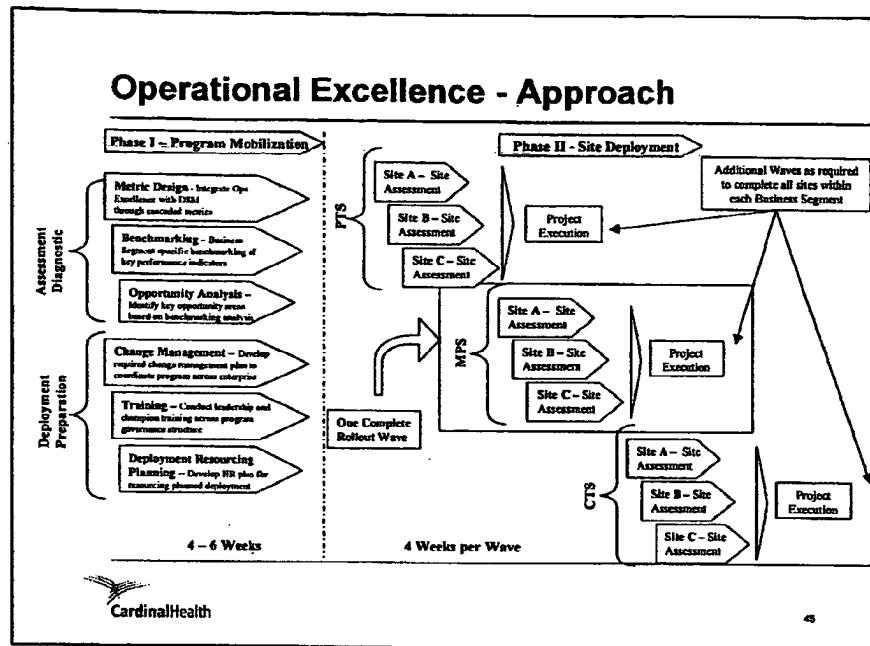


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Deployment Scope

Preliminary CAH Target	\$100M Economic Profit (annualized)
Timeframe	12-24 months
Preliminary Segment Targets	January 26 meeting
Projects per year	3-5 per year per Project Leader
Project Duration	3-6 months
Number of Project Leaders	200
Number of positions backfilled	50

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Next Steps

- Firm up program benefits estimate
- Complete resource requirements planning for deployment
- Buy-in of sponsors
- Identify Champions
- Finalize program scope and timing



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Customer Advocacy

Team members

Jan Dziewior – team leader

Vojna Andrie - MPS

Michele Donatich - MPS

Mico Holguin - PTS

Customer Advocacy

- **Title:** *Implementing Customer Advocacy Throughout Cardinal Health Segments*
- **Benefits:**
 - Improved response to customer experience with closed feedback loops
 - Use of customer information to improve on service/product related issues
 - Source of customer-centric input for future product ideas
 - Improved Customer Satisfaction then Customer Loyalty
- **Costs:** TBD
- **Recommendations:**
 - Develop support and endorsement to proceed
 - Thorough assessment of value of customer advocacy model for each business and segment
- **Timing:** After decision to proceed, full implementation will take 12-18 months



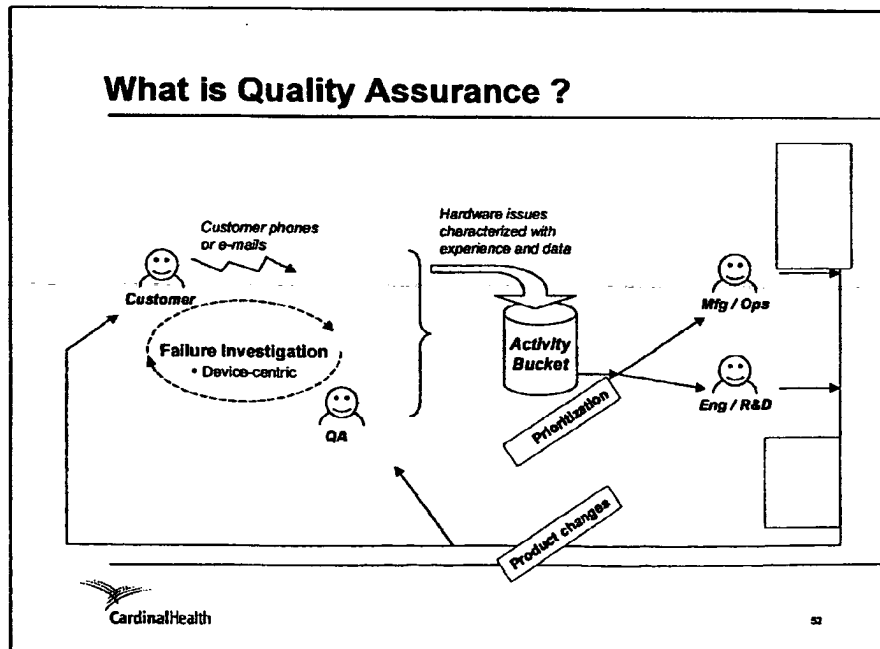
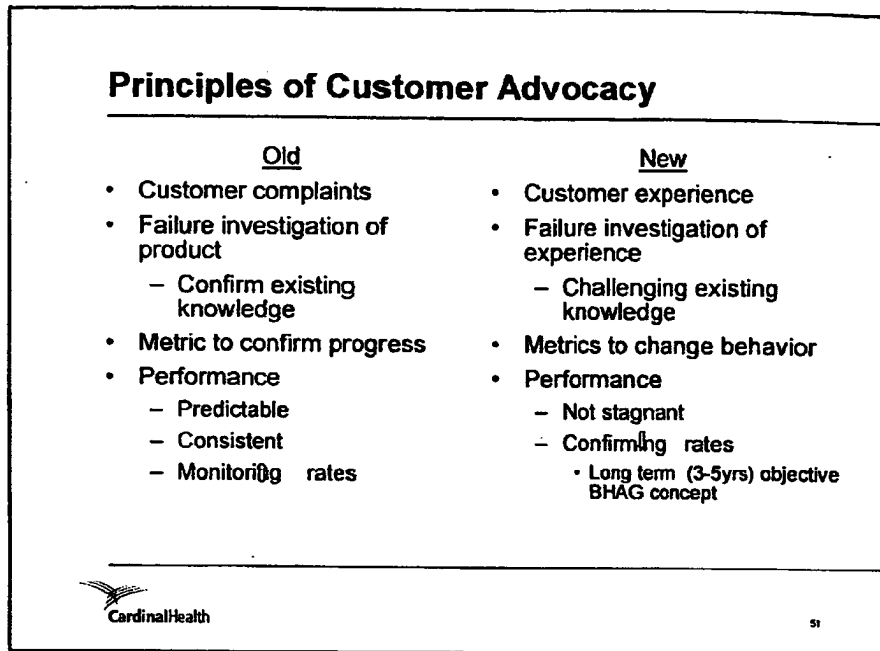
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Future State of Customer Advocacy

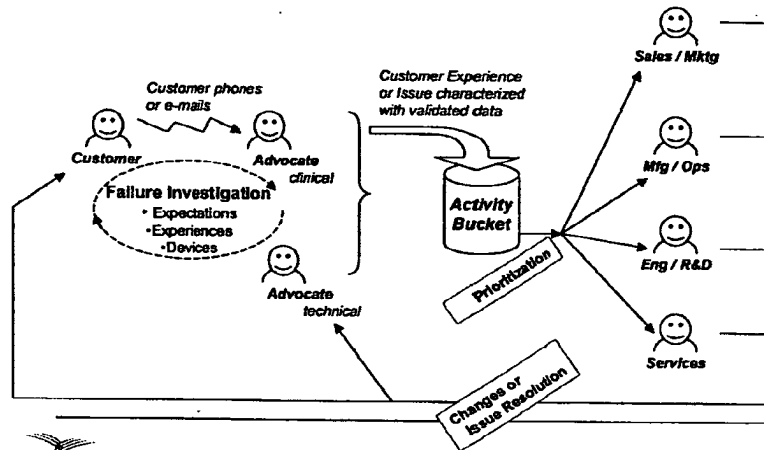
- Establish a customer advocacy group in each segment to manage customer experience to improve customer satisfaction and loyalty
 - A business operating with ever improving efficiency in meeting customer expectations in ways that move the customer to loyalty
- Recommendation #1 – Corporate leadership must establish common cultural beliefs about changing to a customer centric mindset throughout the company
 - Analysis of process & associated resources that it will take to achieve this mindset
- Recommendations #2 - Transitioning into the Advocacy model requires a culture supportive of focusing on the customer and mobilizing potential resources from across the organization
 - Investigate how this impacts activities in other organizations
 - Determine where Customer Advocacy organizationally fits in the business/segment



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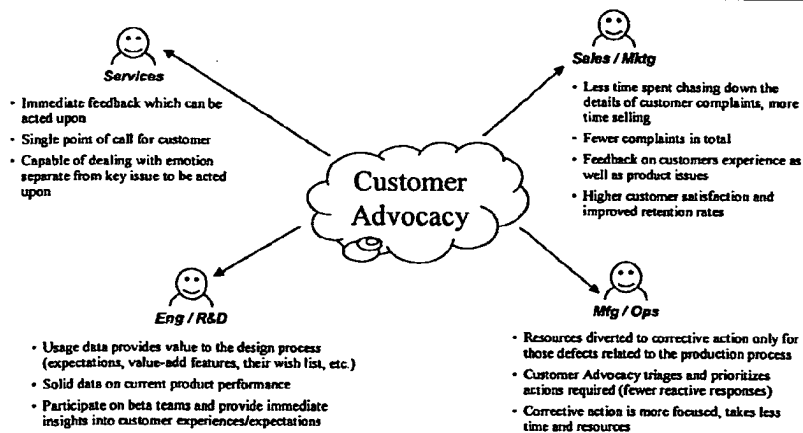
What is Customer Advocacy ?



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Benefits to Other Functions



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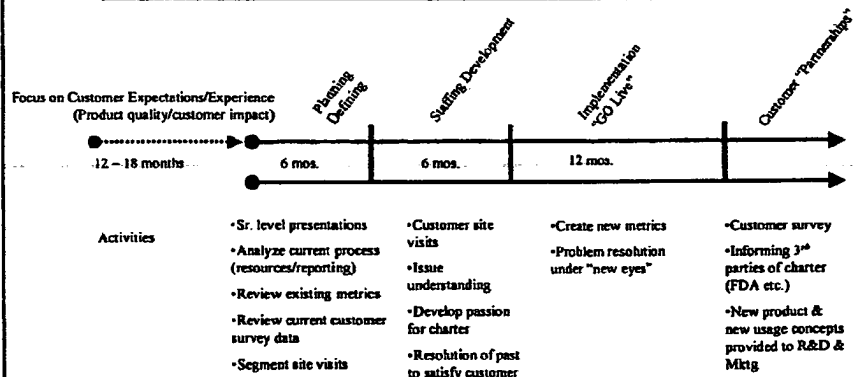
Benefits realized at Alaris

- Captures and acts on service-related defects
 - 75% of customer issues are non-product related
- Consistent & objective Failure Investigation creates valid data on which to take (or not take) corrective actions
 - Drives investigations to root cause (broader than product contribution)
 - Catalyst for product/process enhancements
 - Provides critical systems "thinking" to customer issues
- Other Functions isolated from disruptive / reactive responses to perceived "critical / urgent" complaints
 - Frees up & focuses resources (sales/marketing/operations/R&D)
 - Better utilization of time & resources
- Customers interact with a peer (e.g. RN's) inside Cardinal when submitting complaints
 - Streamlined communication, solid data, viewed as "peer" by customer
- Timely, complete & accurate response to customer complaints with a ↓ of NFF or Cannot duplicate



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Timeline of Changes



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Key Principles and Elements

- Customer-centric – ~~all~~ complaints feedback offers value to the business
- Actions to be taken only on validated data
- Users need a single point of contact for relevant info; this should be a peer
- Corrective action should be prioritized objectively based on severity of failure and customer satisfaction
- Emotions need to be managed and not allowed to drive activities
- Understanding customer expectations & how they were created is the foundation for understanding experiences



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Benefits from Alaris initiative

Old Alaris Model

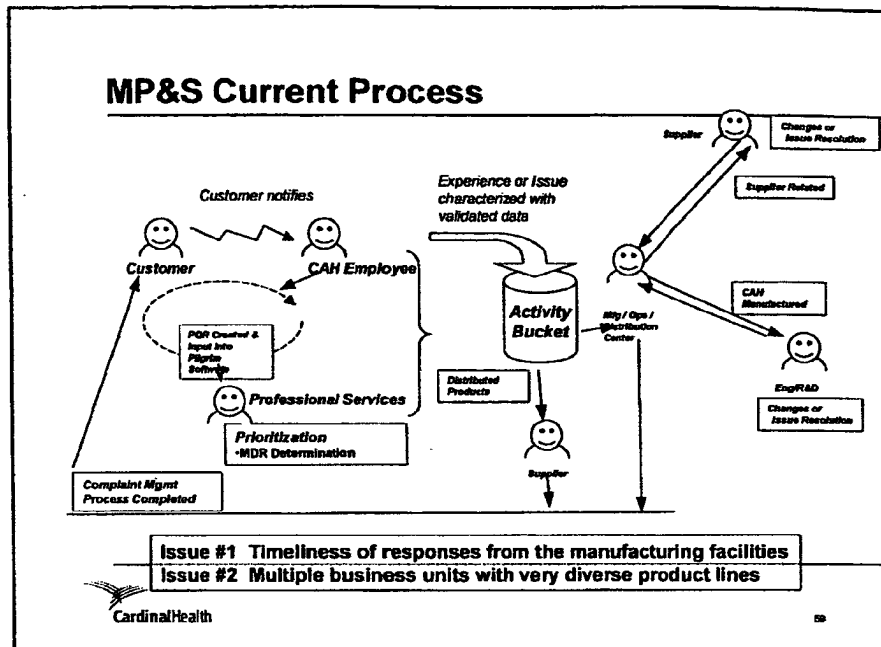
- Complaint process
 - 14 recalls over 4 yrs
 - Warning letter
- Reactionary management
 - Emotion over facts
- Repair rates ~ 95% FYR
23.9 CPM
- Repetitive FI & customer feedback
- Complaint closure >120 days
- Fights FDA
- 20+ FTE's to support comp. mgmt
 - 10 jr. clerks & lab techs
 - 10+ engineers, sales – Med. To Sr. levels of mgmt FTE's

New Alaris Model

- Customer Advocacy
 - 2 recalls over 5 yrs
 - 1 Notice
 - 1 Field action
- Responsive management
- Repair rates ~ 4.85% FYR
7 CPM
- 97% instr. Repair eliminated
- Improved FPY
- Improved initial new prod. Releases
- ↓ travel by multiple depts.
- Improved sales force utilization
- Complaint closure <10 days
- Trains FDA
- 16 FTE's



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Changes Required at MP&S to implement Customer Advocacy

- Need to consider reorganizing reporting structure, (i.e. addition of a Failure Investigation engineer), in order to complete customer complaint management from reporting to closure (including, testing, customer service and clinical).

PTS Current State – Process

- cGMP production requires specific QA response which is usually detailed in site SOP
 - PTS wide process inconsistent
 - Cross BU programs demonstrate issue
 - Written feedback & follow-up for customer review lacking
- Customer development & communication is not consistent before cGMP production.
 - Some customers overwhelmed while others severely neglected
- Despite lack of centralized customer care program, PTS is constantly offered various programs which appear to offer profitability & long-term growth
- Competitors recognize that a positive regulatory standing is a cost of doing business and are searching for programs that will offer customers perceived value



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PTS Current State – Best Practices

- It appears that sites like Red Lion Road may offer a blue print of some best practices that PTS may desire to embrace
 - Established metrics for customer tracking of issues
 - Proven communication template that insures all areas, e.g. sales, operations etc. are rapidly notified and involved in customer complaints



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PTS Current State – Problems/Issues

- Strategic Account Directors are usually first to experience cross BU inconsistencies
 - R&D activities not synchronized. There is not a customer champion to coordinate customer feedback
 - Commercial production when on back order, does not aggressively provide information to customers for adjustments or resolution
- PTS understands regulatory expectations but customer must navigate
 - Batch record review (cross BU even more difficult when a product depends on multiple sites)
 - Deviations
 - Late deliveries
 - Little emphasis on scheduled project or product reviews
 - Audits



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PTS Current State – Problems/Issues

- Customer communication
 - Dependent on experience level of BD rep
 - Limited amount of PM's available for critical programs
 - Defined policy for customer touchpoints has not been formalized
 - Hot Line for frustrated customers not available so customers either call site GM or higher
 - After resolution of customer issue, no process in place to insure resolution was appropriate



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Changes Required at PTS to implement

- Agreement on a customer advocate process that involves all functional areas with specified roles/responsibilities
 - Review Red Lion Road or other mature site for a program that others could follow without incurring additional costs.
- Insure PM's are available & have authority to represent customer at sites and to apply cycle compression at appropriate times
- Loyal customers demand more than regulatory compliance. Senior management must allow for initiatives that build value around our regulatory accomplishments



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Translating this across Cardinal Health

Elements of Communication (Internal & external)	CTS	MP&S	PTS
Customer Advocate is a peer of the User	RN's interact with clinical Engineers interact with biomedical	Clinicians facilitate advocate role	BD Rep, PM or Cust Service performs advocate role depending on drug development cycle
Failure investigation (FI)	Technical advocate – FI product contribution Technical & clinical investigate expectations & practices to explain experiences	Failure investigations are conducted at the manufacturing facility. Business unit engineers and plant quality personnel complete the investigation.	Once into cGMP production, QA SOP drives resolution of technical issues
Actionable feedback to correct process owner	Clinical & Technical advocates drive actionable items to resp. dept. including customer	Clinicians drive prioritization based upon receipt of customer complaints.	Performance metrics required to provide feedback as well to serve as a guide for future strategies



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Translating this across Cardinal Health

Elements of Communication (Internal & external)	CTS	MP&S	PTS
Timely response to customer (Internal & external)	Customer communication is priority throughout investigation Automatic workflow escalation	Manufacturing site has responsibility for complaint closure. Each facility must adhere to P&P. Acknowledgement letters are sent out at receipt of complaint	Every manufacturing site needs to follow a similar response process for customers (Internal & external) to insure site consistency
Corporate review of shared customers	Information readily available through company portals to those authorized Automated cust. Case mgmt tools available to all interacting with cust.	Cross divisional information provided for shared customers when applicable	Cross divisional information provided for shared customers when applicable
Delivering value to customers to differentiate CAH from competitors	Sale & marketing begin using CA to assist in mgmt. of account & competitive differentiator	Strategic initiatives that anticipate customer concerns	Strategic initiatives that anticipate customer concerns

Current State – Estimated Spend

Segment /Name	FTE	2004 Spend
MP&S Professional Services	13	\$0.5M
PTS Customer Service	~10	\$0.5M
CTS Customer Advocacy	16	\$1.9M
Total	39	\$2.9M



Actions to Close The Gap

- **Action #1 – MPS and PTS management decision on where customer advocacy is embedded in the organization**
- **Action #2 –**
 - For each business, begin in-depth analysis of current state supported by data collection on complaints, corrective action, response times and customer interviews.
 - Determine capability needed to migrate to new model (e.g. skills, systems, processes etc.)
 - Estimate requirements, phased implementation and deliverables



00



Stability Testing - PTS

Team members:
Michael Barron - RTP
Michael Hagan – San Diego (Trade Place)
Kathy Nordin - Woodstock
Beth Rhodes – Winchester
Joanne Marriott – Pharmaceutical Development

PTS Stability Testing

- **Consolidate PTS Stability Testing in North America to 2 Center of Expertise sites**
- **Benefits:**
 1. Two CoE implemented utilizing current capacity and capabilities
 2. Run rate annual savings estimated at \$0.7-\$0.9M
 3. 18 HC reduced at seven US sites
 4. Optimized utilization of current equipment and chambers
- **Costs:**
 1. One time costs between \$1.0M - \$1.3M
 - mainly FTE method transfer costs concentrated in first 6 months post initiation extending through 12-18 months
 - other factors include severance and sample shipments
 - minimal equipment and facilities costs



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PTS Stability Team recommends the following -

- **Recommendations:**
 - Transfer stability studies to San Diego from Albuquerque and Woodstock
 - Transfer stability studies to RTP from Humacao, Winchester, St. Pete, Ft. Worth, and Somerset
 - Management must embrace, support, and communicate across all involved sites and facilitate customer buy-in
 - Assign overall Project Manager and identify site project teams
 - Develop Service Agreements and Metrics between donor and recipient sites to meet or exceed current standards for cycle time and quality



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Recommendations, Constraints and Timing

- **Recommendations (cont'd):**
 - Determine applicability of ICA for this program
 - Further study of Europe needed to evaluate feasibility of a stability CoE
- **Potential Constraints:**
 - Site concurrence
 - Customer regulatory concerns
- **Timing:**
 - Initiate process immediately upon approval
 - Process completion 12 to 18 months



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Future state of PTS Stability testing sites

- **Two stability testing CoE's in N.Am., at San Diego, CA and RTP, NC, that serve all N.Am. dosage form manufacturing and packaging services.**
 - Recommendation #1: Transfer stability studies to San Diego from Albuquerque and Woodstock
 - Recommendation #2: Transfer stability studies to RTP from Humacao, Winchester, Ft. Worth, St. Pete, and Somerset
 - development stability stays, only move stability around time of tech transfer
- **Team did not examine raw material, in-process or finished product testing, assumption is that each mfg site retains it's own raw material, in-process and finished product release testing capabilities**



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Center of Expertise Detail

- Two CoE's implemented at sites already equipped to handle stability studies
 - Current organizations are capable of receiving without appreciable equipment, facilities or headcount changes
 - Favorable FDA inspection for both sites within last 2 years
 - Chambers and storage conditions already in place
 - Kaye Labwatch/backup systems/power generators
 - No additional FTE required to transition
 - No unique equipment required to transition



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Center of Expertise Detail

- Quality and turn-around times maintained at current levels or better
 - Negotiate service agreements with donor sites
 - Develop cycle times and report metrics
- On-going studies transferred except when last timepoint pending or customer/regulatory issues
- Most studies can be transferred within 12 months



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Benefits Detail

- FTE reductions (18) at donor sites create on-going savings
- Technical staff, equipment, and chamber utilization at RTP and SD will be optimized
- Potential for new revenue based on focused CoE
- Donor sites focus on in-process and finished product testing



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Benefits Detail - Assumptions

- RTP and SD were selected as "recipient" sites
 - RTP ← Winchester, Humacao, Somerset, St. Petersburg, Ft. Worth
 - S.D. ← Albuquerque, Woodstock
- Customer approval required
- CBE filing must occur for approved products.
- Equipment is generally left at the donor site for other shared usage, some may have minor salvage value
- RTP & SD need no appreciable FTE or equipment increases to take on the transferred business



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Benefits Detail - Assumptions

- Test Method transfer is on average a 2-3 wk process/method and has been "priced" at 20 transfers/person/yr
- Samples within current studies need to be shipped under controlled conditions to recipient sites, est \$20k /site
- Some stability testing will be left in place to run its course, all new studies would be moved
- Revenue/Profit relief will be given to the donor sites
- No costs to be incurred by the donor sites



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Current State of PTS Stability Testing Process

- **Nine PTS manufacturing sites** including three Pharmaceutical Development sites in the USA perform stability testing.
- **Albuquerque, Winchester, Ft. Worth** constitute majority of stability studies conducted on PTS manufactured product.
- **San Diego and RTP** conduct greatest number of studies under contract services basis, products may or may not be manufactured by CAH.
- Customers may use Cardinal Health, their own labs, or other contract labs to perform commercial product stability testing.
- Testing performed in PTS manufacturing sites use bench equipment shared for in-process and final product release testing



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Current State Spend

- Spend could not be captured
 - Most PTS sites incorporate stability costs into mfg contracts and QC budgets
- Details of all the sites were collected
 - BU point of contact, active and ongoing studies, financials, equipment, chamber details



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Current State – Problems/Issues

- Under-utilized capacity at two main stability hubs in SD and RTP
- Headcount needed to conduct stability studies at multiple sites
- Level of control, i.e. validated monitoring systems, back-up generators, etc.
- Lost opportunities for revenue due to lack of awareness of stability capabilities across PTS



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Actions to Close The Gap - Consolidate testing at two sites

- Management must embrace, support, and communicate across all involved sites and facilitate customer buy-in
- Assign Project Manager
- Gain customer approval and facilitate CBE-30 filings
- Develop Service Agreements/Metrics between donor and recipient sites to meet or exceed current standards for cycle time and quality



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Actions to Close The Gap - Consolidate testing at two sites

- Determine applicability of ICA for this program
- Transfer analytical test methods
- Transfer samples under controlled conditions
- Reduce headcount committed to stability at mfg sites
 - Each site determines appropriate course of action
- Train technical and sales staff on capabilities and capacity of Stability CoE



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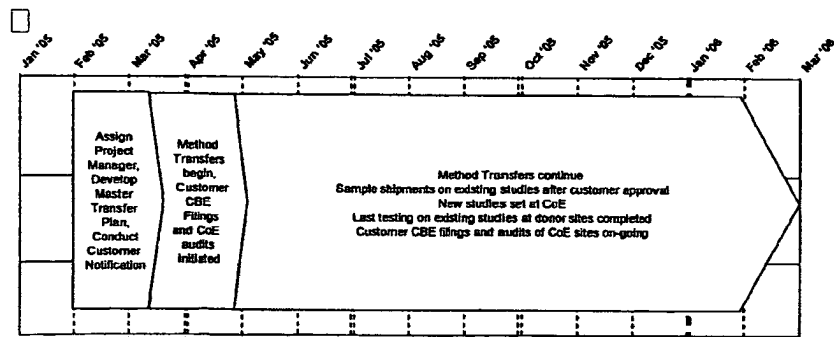
Costs to Close the Gap

- \$1.0M - \$1.3M
 - Method transfers are largest part of total cost and are conducted by CoE staff in conjunction with donor site staff
 - Other factors include severance and sample shipments
 - Ancillary costs associated with transition teams
- Undetermined costs to customers incurred due to CoE audits and CBE filings
- New customer audits increase demands on CoE QA units
- Incorporate new capabilities into technical staff orientation across PTS



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High Level Project Plans



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PTS Supplier Qualification/Certification Process

Team members:

Ed Koenig
Greg Lane
Trevor Lewis
Rick Mucci
Regina Rhoa
Andy Tapper
Ed Thiele

Standardization of the PTS Supplier Qualification/Certification Process

- **Benefits:** \$ 0.350 MM : Enable \$ 4-6 MM annual savings in raw material costs
- **Costs:** \$ 0.250-0.350 MM
- **Recommendations:**
 - 1 Standardize both the qualification and certification process for suppliers
 - 2 Perform all qualification testing at one laboratory
 - 3 Coordinate supplier audits at the PTS level
 - 4 Evaluate consolidation of U.S. Sterile raw material testing
- **Timing:** 6-9 Months



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PTS Supplier Quality Future State

- New Suppliers are qualified rapidly using a standard process. All qualification samples are tested at the same laboratory.
- A standard method to certify suppliers for the reduced testing program is implemented
- Audits of suppliers are controlled at the PTS level and conducted according to a standard checklist and a predetermined plan by plant personnel
- Auditors are trained to audit in a consistent manner
- Where appropriate raw materials and components are tested in a central location



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Benefits Detail

- Savings due to headcount reduction from 80 to 75 people to perform raw material testing
 - Combination of reduced testing due to global use of supplier certification, and consolidation of raw material testing where appropriate (sterile)
- Reduced travel expenses (\$100K/yr) due to changing which sites perform supplier audits
- Soft Benefit: Enable Purchasing to reduce the cost of raw materials by \$4-6 MM . Reduce the time to approve new suppliers by 2 Months
- Ensure that supplier audits are performed in accordance with a standardized schedule to meet GMP compliance requirements



30

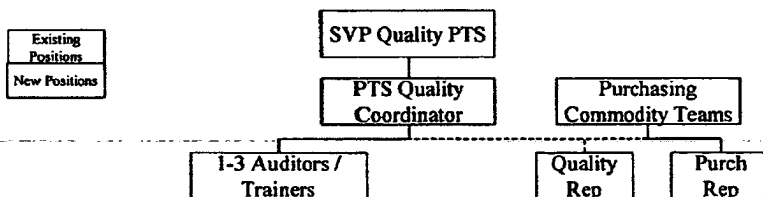
Benefits Detail - Assumptions

- 2 month reduction in Qualification process is not consumed by customer or regulatory approval
- Most of the time in the Qualification process is Non-Value Add
- All plants will agree to and use standardized processes
- Commodity buyers will be co-located at individual sites with quality representatives
- Purchasing group will help drive the Qualification process



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Center of Expertise – PTS Supplier Quality



Responsibilities of Quality Coordinator:

- Maintain standard supplier audit/qualification/certification processes
- Schedule supplier audits
- Train site auditors
- Maintain database for approved suppliers

Interactions with Coordinator and Sites:

- Accountability and Responsibility of audits remains at Site Level. Coordinator will consolidate site plans into overall PTS audit plan, and coordinate site level activities.



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Current State - Spend

<u>Activities</u>	<u>Spend</u>
Raw Material testing	\$4.8 MM (80 people @ \$60,000)
Auditing and certification	\$0.9MM (15 people @ \$60,000)
Purchasing of :	
Raw materials	\$181 MM
Packaging supplies	\$118 MM
Note: 4,800 Suppliers 14,700 Items	



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Current State – Problems/Issues

- No standard process for Supplier qualification or certification.
- It takes too long to qualify new suppliers
- No standard schedule for supplier audits and no system for insuring that suppliers are audited as planned (compliance)
- No method for capturing actual costs of Supplier Audit, Qualification/Certification programs
- No visibility to audits of potential new suppliers



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Actions to Close The Gap

- Hire the coordinator and select the project team
- Create the standardized PTS processes for Audits, Qualification and Certification
- Obtain approval from all sites
- Train site audit teams
- Implement the proposed changes



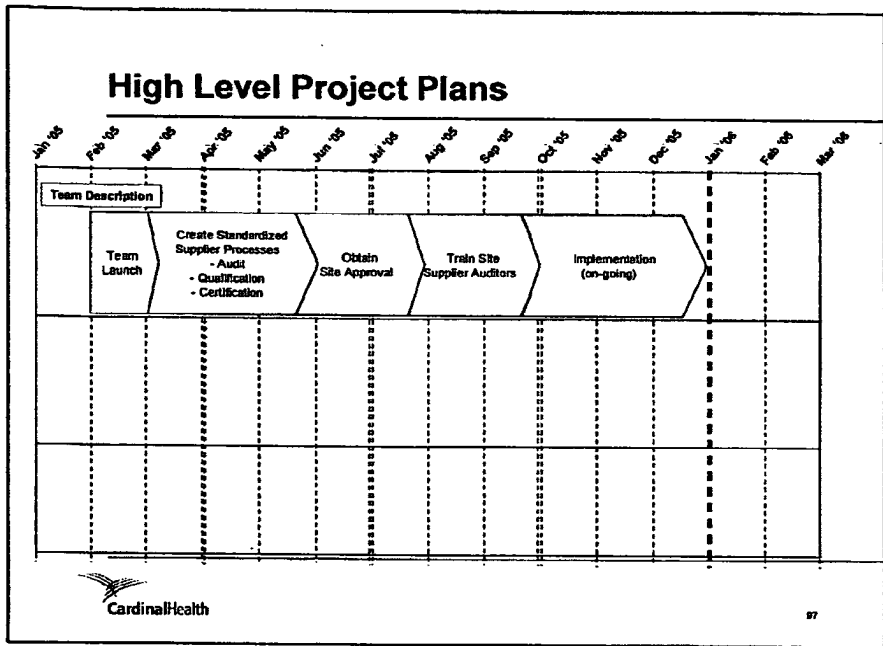
95

Costs to Close the Gap

- Coordinator: \$100K (ongoing)
- Project Team: \$150K (3-4 people for 4 months)
- Optional cost for centralized auditors: \$210K (3 people @ \$70K)
- Note 1: these costs do not include the actual costs to perform audits
- Note 2: total costs to perform audits will increase when full compliance to audit schedule occurs



96

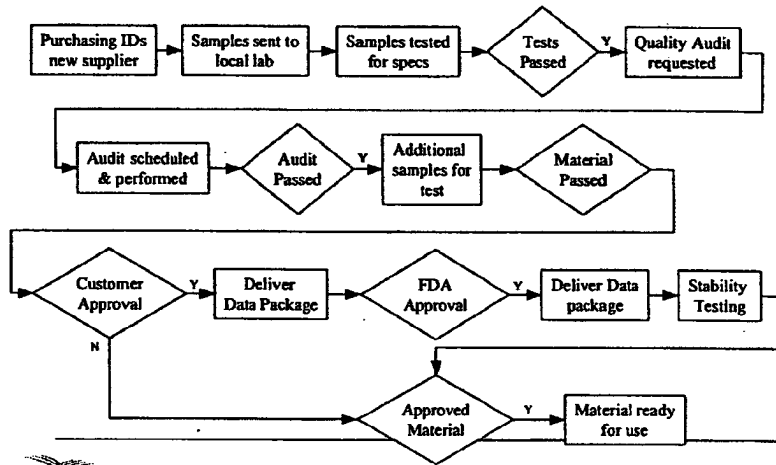


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Appendix

Current State Process Maps

Supplier Qualification Current State Process



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Supplier Certification Current State Process

No standard process exists today

Example process: no standards for * process steps



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Supplier Audit Current State Process

No standard process exists today

- Default is every 2 yrs by site using material
- Same supplier may be audited by more than one site
- All sites develop and audit own plans & schedules
- There is a standard audit checklist for Oral & Pkg Svcs
- Fledgling Audit database (Trackwise)



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PTS - Validation

Team members

Werner Bossert – team lead
MaryBeth D'Argenio
Anserd Fraser
Curtis Monnig
Anthony Pavell
Ted Thom
Dan Blackwell ATK/George Group

PTS Validation Shared Services

Develop a PTS Validation Center of Expertise and enhance existing Computer Validation team

- **Benefits:** Full Run Rate Savings: \$ 0.75 – 1.0M
- **Costs:** One-time costs: \$ 0.5 – 0.8M



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The PTS Validation Team Recommends the following:

- **Recommendation #1**
 - Installation of Validation Expert Team(s) (5-6 FTE's) covering Sterile Technologies, Oral and Packaging Technologies and Analytical Validation at PTS level.
 - IQ, OQ, PQ, Cleaning Validation, Product specific Validation, Process Validation
- **Recommendation #2**
 - Strengthen existing Computer Validation Expert Team (+ 2 FTE's).
 - Software and Hardware
- **Timing:** Implementation Timing: 9 - 18 months



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PTS Validation Activities (Future State)

Site Activities	Business Activities	Segment (PTS) Activities
Based on common standards, templates, SOP's <ul style="list-style-type: none"> - Prepare specifications, protocols, local SOP's - Execute protocols - Write reports - Audit site specific vendors - Provide site specific training - Project management 	None	<ul style="list-style-type: none"> - Establish and maintain common validation standards including product transfer - Establish and maintain common specifications (e.g. HVAC, water system, hardware, ...) - Establish and maintain common templates and high level SOP's - Establish and maintain repository of validation data - Audit vendors for enterprise wide equipment, facilities, software, hardware - Provide guidance and advice on best practices and regulations - Give training support on validation (see training Initiative) - Perform full validation service including execution for major projects and enterprise wide software implementations (e.g new facilities, new technologies, JDE, Doc. Harmonization, ...)



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Center of Expertise Detail

- Validation Expert Teams should report to the PTS Quality Head with dotted line to the Business Quality VP's
- Responsibilities - see description of future state. Important role is consultancy to the sites and Quality VP's.
- Common standards, templates and high level SOP's to be approved by PTS Quality Head and Business Quality VP's.
- The Validation Expert Team members need knowledge in global regulatory requirements.
- Existing Computer Validation Team and the Computer Validation Council could be a model



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Benefits Detail

- Common approach to Validation
- One face to customers and agencies
- Leverage validation documentation and expertise
- Leverage vendor audit findings and recommendations
- Implement / use best practices
- Reduce consultancy expenses by 40%
- Will enhance regulatory compliance
- Will allow to close existing compliance gap with existing personnel or reduce number of people to be hired (depending on local situation)
- Know-how will stay within the company



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Benefits Detail - Assumptions

- The consolidated data are based on the replies of about 70% of the sites, for those which did not reply the numbers have been estimated.
- Savings of 40% of the consultant expenses are based on reasonable estimates of the team members. Consultants will also be needed in the future state for peak situations.
- Cost of non-compliance and benefits of improved customer satisfaction due to the future state have not been calculated / estimated.



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Benefits Detail - Assumptions continued

- For the installation of the Validation Expert Team(s) a period of 3-6 months for recruitment and another 3-6 months for being effective is expected. This could be shortened, if internal candidates will be found.
- The breakdown of the validation activities have been calculated based on percentages given by those sites which gave detailed information.
- The proposed size of the Validation Expert Team(s) is based on the current business. If major validation projects are upcoming or the business model changes, the team(s) must be adjusted.



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Benefits Detail - Points to consider on implementation

- An evaluation of the site level staff was not part of this exercise. So no recommendation on headcount impact at a site level of the future state can be given.
- The validation expert team members need knowledge on global regulatory requirements.
At least 2 senior validation experts with significant experience in pharmaceutical validation, 2 medium level members and admin support is recommended.
- Local requirements and responsibilities (e.g. Qualified Person) have to be considered.
- Local documentation has to be in local language.



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Benefits Detail - Points to consider on implementation

- Standardization of equipment within the same technology would contribute significantly to the shared service approach as well as common suppliers for major equipment/facilities and common consultants.
- Product specific validation are usually significantly impacted by customer requirements.
- Once the expert team is working, the knowledge of subject matter experts from the sites should be used (e.g. cleaning validation, lyophilization, etc.)
- The proposal only covers the pharmaceutical business. Within PTS there is also H&N and cosmetic business.



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Current State of PTS Validation Process

- Currently all validation activities are at site level, except some activities in computer validation as indicated.
- Validation activities include:
 - Establish system specifications (URS, Design Specifications,...)
 - Vendor qualification (equipment, facilities, hardware, software)
 - SOP writing
 - Protocol writing
 - Pre-validation activities
 - Execution of validation and qualification
 - Report writing and assessment
 - Re-validation activities
 - Analytical work
 - Calibration activities
 - Customer related activities
 - Project management
- Computer Validation: Master Plan and URS, common templates and high level SOP's currently being established at Segment (PTS) level
- Some standards currently available at PTS level



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Current State - Spend

Total in all validation activities, including Computer Validation

- Head count allocated [FTE's]: ~ 206
- Other expenses internally [\$]: ~ 1,087,000
- Capital expenditures [\$]: ~ 2,738,000
- Consultant expenses [\$]: ~ 2,967,000
- Customer reimbursement [\$]: ~ 2,224,000

Based on feedback of about 70% of the sites



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Current State – Problems/Issues

- Individual Validation approach at site level, different levels and standards
- At most sites deficiencies in validation
- No common face to customers and agencies
- Significant expenses on external consultants
- Sharing of best practices limited
- Reinventing the wheel at the sites
- Different interpretations of legal regulations



114

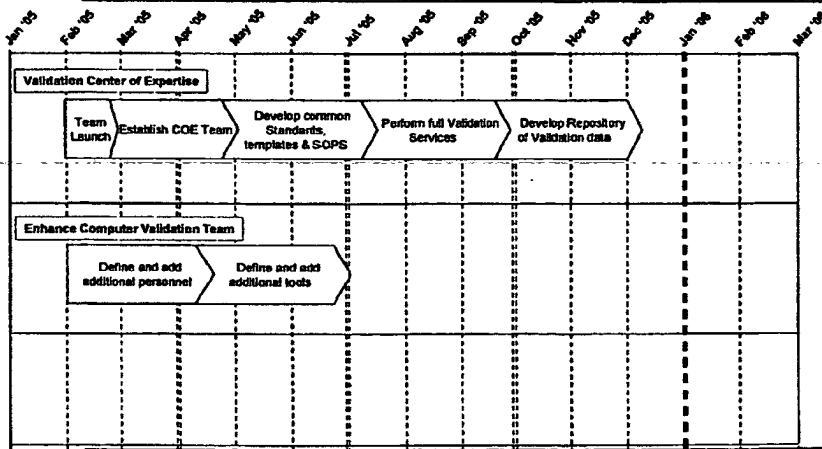
Costs to Close the Gap

- Personnel costs of the Validation Expert Team: 5-6 FTE's for validation and 2 FTE's for computer validation (\$ 0.75 – 1.0M)
- Recruitment costs
- Offices and equipment for the team(s)
- Hard- and software to establish a repository of validation activities (one-time costs of \$ 0.5 – 0.8M)



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PTS Validation Team - High Level Project Plans



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Appendix

Current State Spend Detail

Current State - Spend

Site / Business Unit: Oral Technologies

Activities	Head Count allocated FTE's	Other Expenses Intensity (\$)	Capital Expenditures (\$)	Consultant Expenses (\$)	Number of transactions in FY05	Customer reimbursement (\$)
Validation Activities						
System specifications (URS, Design spec.)	0.81				43	
Vendor qualification (equipment, facilities)	0.43					
SOPs	1.7325					
Protocol writing	7.83		45,144.00	103,057.88	239.4	
Execution	26.3025	9,521.28	1,136,059.81	136,382.34	782	723,617.28
Calibration	5.58	11,801.80	35,704.80	784,215.52	2430	
Report writing and assessment	8.01	7,140.88		125,680.90	250.2	118,800.00
Prevalidation activities	1.575					
Revalidation activities	0.81					
Test methods	3.06					
Analytical work	10.88	71,405.60			27	108,000.00
Customer related activities	0.81					
Project management	7.11				239.4	
Total	75.24	89,973.44	1,218,658.41	629,356.61	4023	850,417.28

Consolidated data from all OT sites based on reply from 8 sites and estimated for 5 sites



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Current State - Spend

Site / Business Unit: Packaging Services

Activities	Head Count allocated FTE's	Other Expenses internally (\$)	Capital Expenditures (\$)	Consultant Expenses (\$)	Number of transactions in FY05	Customer reimbursement (\$)
Validation Activities						
System specifications (URS, Design spec.)	0.63	0	17080		47.6	
Vendor qualification (equipment, facilities)	0.51	3400	17080		5.1	
SOP's	1.05	0	17080		20.4	
Protocol writing	8.814	0	17080	29,750.00	787.3	
Execution	10.404	23800	17080	12,750.00	447.1	68000
Calibration	0.17	4250	8890		3.4	
Report writing and assessment	0.252	0	17080		783.9	
Revalidation activities	2.04	0	0		39.1	
Revalidation activities	1.87	0	0		64.4	
Test methods	0.17	0	0		10.2	
Analytical work	1.18	78900	27200	34000	37.4	54400
Customer related activities	0.425	0	0		51	527000
Project management	0.782	0	17080		34	
Total	30.277	111,350.00	137,700.00	76,500.00	2340.9	849,400.00

Consolidated data from all PD sites based on reply from 3 sites and estimated for 2 sites.



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Current State - Spend

Site / Business Unit: Pharmaceutical Development

Activities	Head Count allocated FTE's	Other Expenses internally (\$)	Capital Expenditures (\$)	Consultant Expenses (\$)	Number of transactions in FY05	Customer reimbursement (\$)
Validation Activities						
System specifications (URS, Design spec.)	1.36	0	0	0	0	0
Vendor qualification (equipment, facilities)	0	0	0	0	0	0
SOP's	2.04	0	0	0	0	0
Protocol writing	5.88	0	0	0	0	0
Execution	14.5	0	0	448,500.00	0	0
Report writing and assessment	0.885	0	0	0	0	0
Revalidation activities	0	0	0	0	0	0
Analytical work	0	0	0	0	0	0
Project management	3.835	0	0	0	0	0
Total	34.3	0.00	0.00	448,500.00	0	0.00

Consolidated data from all PD sites



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CardinalHealth

Operation One Cardinal Health Executive Presentation and Decisions on Quality

January 13, 2005

1

The Quality Function has 2,270 FTEs representing total costs of \$143.2 M (*)

Quality FTE's represent <1 % of total NON PD/PS Value of Production of \$15.4 B or 3% of \$5.0B Value of Manufactured Goods.

Area	FTE's	Area	Costs (M)
Corporate Quality		Personnel Costs	
• Management	4	• Corporate	\$3.5
• Staff	10	• MP&S	\$27.8
• Admin	2	• PTS	\$67.3
Total Corporate Quality	16	• CTS	\$19.7
		• PD/PS	.5
		Total Personnel Costs	\$118.8
Business Segments		Other Costs	
• MP&S	932	• MP&S	\$6.0
• PTS	1078	• PTS	\$12.9
• CTS	233	• CTS	\$5.5
• PD/PS	11	• PD/PS	n/a
Total Quality/Segment	2,254	Total Other Costs	\$24.4
Total Quality FTE's	2,270	Total Quality Costs	\$143.2



Source: Quality Shared Services Attachment A for FY 2005 YTD + forecast

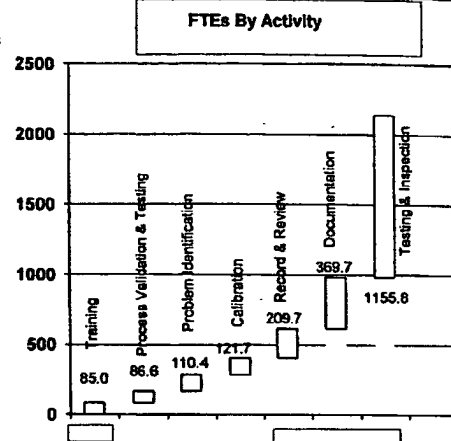
(*) does not include 902 shadow FTE's and costs of \$50M from admin, line and management

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Activities performed by the Quality Organization

Across all segments, 60% of the FTEs are involved in the Basics of Quality Activities

- Testing and Inspection
- Documentation
- Record and Review
- Calibration
- Problem Identification
- Process Validation & Testing
- Training



Source: Quality Shared Services Attachment B Survey

Overall, the Quality Function is in Stage II of Excellence with segments varying in problem identification

Key takeaways:

- Clear and strong alignment of Quality to business unit goals
- Quality is tactical rather than strategic (e.g. customer focused) although the desire to become more strategic exists
- Problem Identification has greatest variation across segments with opportunity to improve using common methods and tools
- Span of Control at Stage IV – good for autonomy and cost containment but has strategic and governance downside.

Overall Stage Assessment:

- Performance in stages vary by businesses and segments.
- Need to improve by driving for consistency
- Build capability and talent in all segments
- Leverage use of experts and sharing of methods and practices in a centralized structure.

Quality	I	II	III	IV
Strategic Alignment		X		
Overall Quality				
- Customer Service		X		
- Performance Improvement		X		
- Compliance				
Problem Identification		X		
- PTS		X	X	
- MP&S		X		
- CTS			X	
- PD/PS			X	
Metrics		X		
Span of Control				X
Overall Position		X		



Internal Client Perspective of QRA

QRA Model

- Quality is not a mindset at Cardinal Health– we are not proactive
– This is not high enough priority today
- When financials are tight– quality suffers
- Corporate Quality organization– not sure what their role is or should be
- Need to understand roles and what will be at Business or Segment level
- Corporate centers of excellence would be of value
- Would like to see stronger regulatory (i.e. FDA) affairs– could be a strategic advantage

People

- Under resourced today
- People we have are good– don't have enough bench strength
- Need to upgrade and deepen talent
- Not enough people

Processes

- Keeps us out of trouble but not very proactive or innovative
- Site level measurements and incentives can hinder investment in quality
- Surveys are good but not always timely
- Limited policy standardization



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Corporate and site Quality organizations are lean compared to benchmark companies

The corporate quality organization has a ratio to Business Quality FTEs of 1:141 which is much leaner than other companies of similar size and business/product offerings.

Company	A	B	C	D	E	F	Cardinal Health
Quality FTE's at Site	5,000	2,103	635	506	82	1,899	2,254
Corporate	65	228	34	122	9	276	16
Total	5,065	2,232	66	628	91	2175	2270
Ratios	1:77	1:9	1:19	1:4	1:9	1:7	1:141

The ratio of Quality to Manufacturing people is 1:14 which is leaner than other benchmark companies

Company	A	B	C	D	E	F	Cardinal Health
Quality Roles (1)	5,075	2,331	633	619	91	2,292	2,270
Total Mfg Roles	35,000	9,383	4,000	2,549	2,002	11,076	31,825
Ratios	1:7	1:4	1:6	1:4	1:22	1:5	1:14

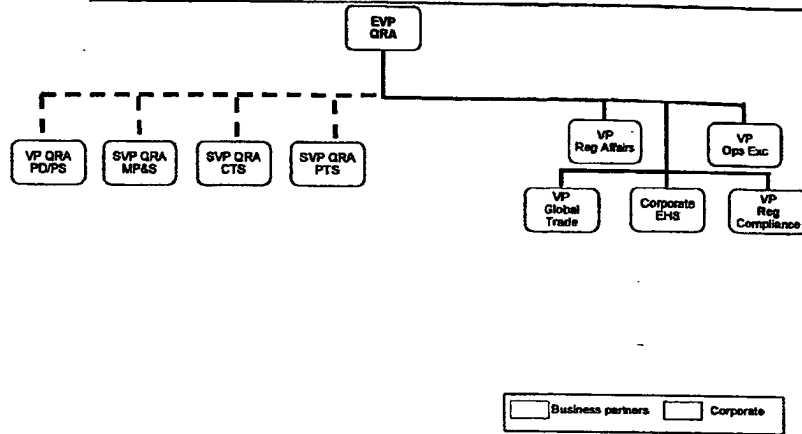
Benchmark companies in alphabetical order are: Abbott, Alcon, Eli Lilly, GlaxoSmithKline, Johnson and Johnson, Medtronic and Wyeth



Source – Best Practices L.L.C. – The Quality Function, Structure, Staffing and Execution, pp.26
(1) Quality roles includes personnel at corporate and sites (2) Cardinal Health Data from Attachment A

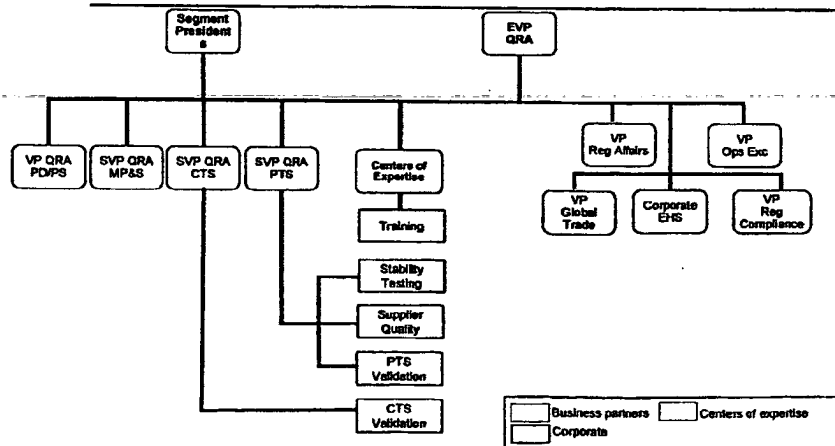
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Current state - Quality organization



7

Future state - Quality organization



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Capability Opportunities are at least \$110M with one-time costs of \$7-\$13M and recurring investments of \$7.4M

Operational Excellence

Specific Recommendation	Benefit	Investment	Quality Impact	Service Impact
<ul style="list-style-type: none"> • Create an Operational Excellence capability • Align Operational Excellence with DSM process • Attain business commitment to staff and drive operations excellence initiatives • Establish Corporate Ops Exc CoE (4 Segment Deployment Champions & 14 business directors) 	\$ 100 M annualized	One-Time: \$8.5-12.5M (Includes Assessment, Training, Deployment, IT Solutions) Ongoing Investment of \$6.5M (18 FTE and 40 FTE backfill)	<ul style="list-style-type: none"> • Performance to target • Minimized cost of process infrastructure and non-conformance 	<ul style="list-style-type: none"> • Performance matched to customer value • Generate solutions to fit needs

Audit & Compliance

Specific Recommendation	Benefit ⁽¹⁾	Investment	Quality Impact	Service Impact
<ul style="list-style-type: none"> • Establish medical device regulatory counsel • Establish compliance analysis capability • Establish EH&S audit and metric capability • Add corrective action and facility operations capability 	Avoid Lost Earnings \$10 M Avoid Corrective Action Costs: \$1.5M Avoid Legal costs: \$0.5M (FY06) Avoid Consultant costs: \$2.5M	One Time: \$0.2 M for verification of audit program Ongoing Investment of \$0.9M (8 FTE)	<ul style="list-style-type: none"> • Elimination of disruptive regulatory issues • Ability to correct problems • Achieve baseline EHS capability • Understand risks 	<ul style="list-style-type: none"> • Eliminate risks to strategic initiatives • Aligns acquired operations to standards • Enables influencing regulatory policy

Notes: (1) Audit and compliance benefits are cost avoidance and therefore not included in totals



CardinalHealth

Centers of Expertise opportunities range from \$3.0M - \$4.3M with one-time costs of ~\$1.5M and recurring investment of ~\$1.5M

Opportunity	Specific recommendations	Baseline \$\$ & FTEs	Benefit Range (\$)	Quality Impact	Service Impact	Investment required	Timing
Quality Training	<ul style="list-style-type: none"> • Create a corporate training center to provide guidelines on training needed to meet regulatory requirements and monitor training effectiveness • Consolidate MP&S and PDPS Distribution curricula • Provide Web based e-learning where applicable 	Baseline = 0 (No corporate training activity)	\$0.8 - \$1.2 M/yr Reduced training hours per site	Improve training to reduce observations and warning letters	Web based Training saves 48% labor time, improves student retention & provides consistent materials and delivery	\$350 K CapEx 4 redeployed FTEs (\$0.3M) 2 incremental FTE (\$0.2M) Note: LMS and Portal in IT	MP&S / PDPS Start in Jan/Feb Corp Training start up March '08
Stability Testing - PTS	<ul style="list-style-type: none"> • Transfer stability testing from 6 "donor" sites to 2 other existing sites in North America (RTP, SD are the "recipient" sites) • No material change to the assets employed at the 6 "donor" sites 	~ \$20M ~ 80 FTEs	\$0.7 - 0.9 M Savings from reduction of 13 FTEs at donor sites Revenue gains for stability tests possible in the long-term	Test quality is equivalent across all sites, better equipment in place at RTP & SD	Maintain the current test turnaround time of 15-30 days	\$1.0 - 1.3 M Relocation of samples, transfer of analytical methods, and full-time program mgmt. for 15 mos.	9-18 months duration
Supplier Quality - PTS	<ul style="list-style-type: none"> • Implement segment level CoE for Audits & Qualification. • Standardize Audit Qualification Process across PTS 	20 FTE PTS	\$0.75 - 1.2 M PTS	Improve compliance capability and internal SOP Reduce Audit overlap	Reduce Cycle time to lead time to set up and audit new suppliers	5-6 FTEs incremental \$0.4 - \$0.5 M/yr.	6-12 months duration
Validation & Qualification	<ul style="list-style-type: none"> • Implement Validation Expert team to cover Sterile, Oral, Pkg and Analytical Validation • In PTS, replace ~40% of consulting spend with 5-6 internal FTEs at a segment 	\$3 M of spending on consultants 130 FTEs, primarily at sites	\$0.75 - 1.0 M 25-40% reduction in spending on consultants	Improve internal capabilities	One face to customer and agencies Improve cycle time of validation	5-6 FTEs incremental \$0.4 - \$0.5 M/yr.	6-12 months duration



CardinalHealth

Summary of Changes & Implications

Major Changes

- Adopt and fund customer driven Operational Excellence as a core element of One Cardinal Health
- Upgrade regulatory compliance to minimum capability
- Utilize compliance function for corrective programs
- Operationalize changes to corporate and segment management structure
- Implement CoE consolidation and recommendations

Implications

- Commitment to resource Operational Excellence and compliance capabilities
- Commitment to soliciting customer feedback and aligning processes to customer value proposition
- Internal deployment against problems vs. external regulatory consultants
- Seamless connectivity between operations and Quality in priorities, rewards and actions
- Operational assessment input into business strategy and initiatives
- Redeployment of resources to achieve shared services Center of Expertise consolidation



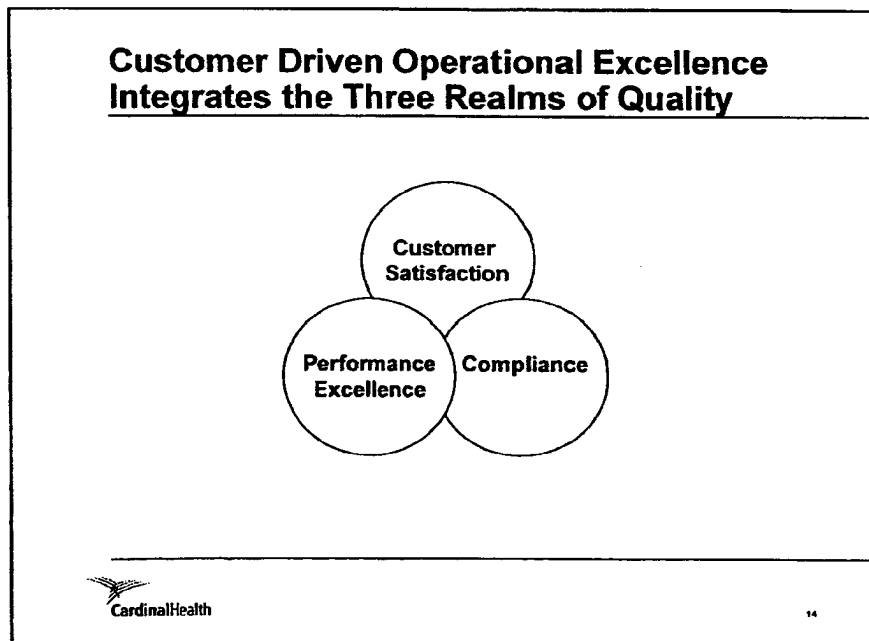
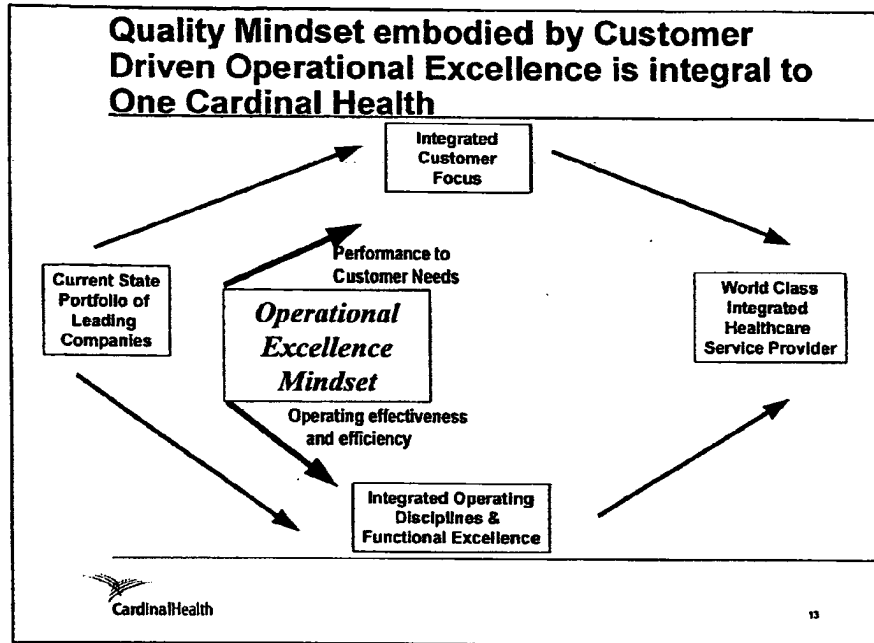
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Operation One Cardinal Health Quality's Role in One Cardinal Health

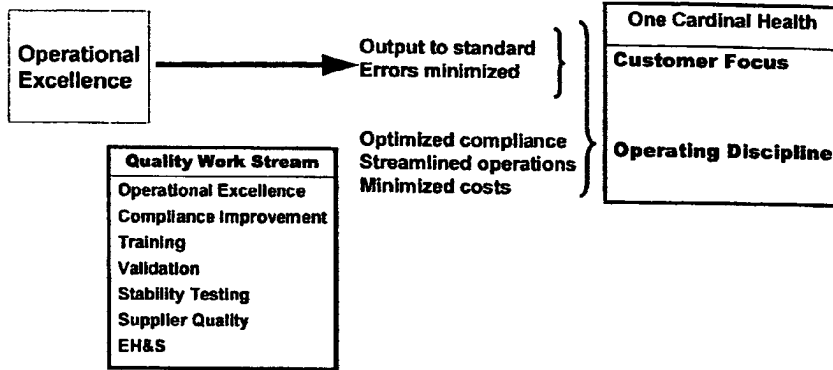
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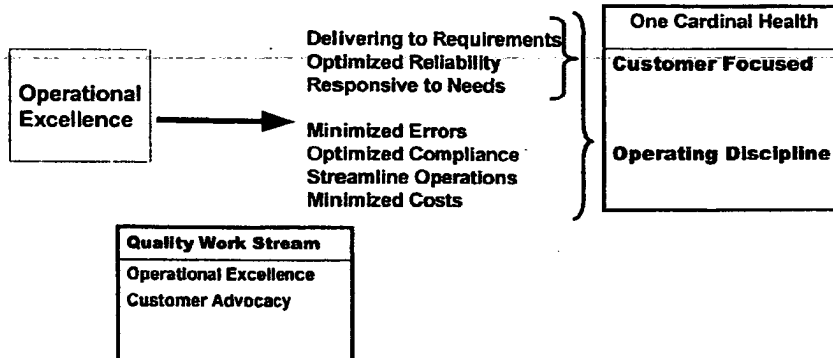
Internally focused Operational Excellence

- Delivers operating discipline with some customer focus



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Customer driven Operational Excellence is both externally and internally focused and delivers customer focus in addition to operating discipline



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